IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

MARK TASSINARI, RICHARD ESPINOSA, and JOSEPH ALMEIDA, individually and on behalf of all others similarly situated, *Plaintiffs,* vs. THE SALVATION ARMY, A NEW YORK CORPORATION, *Defendant*.	Civil Action No. 1:21-cv-10806-LTS

SECOND SUPPLEMENTAL DECLARATION OF DR. CLAUDIA P. RODRIGUEZ IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

I, Claudia P. Rodriguez, MD, declare as follows:

1. I previously provided a Declaration and Report in Support of Plaintiffs' Motion for Preliminary Injunction, dated May 3, 2023 (ECF 143 to 143-5) ("Rodriguez Decl.") describing my background and experience and expert opinions regarding Opioid Use Disorder (OUD) and Medication for Opioid Use Disorder (MOUD). I also provided a Supplemental Declaration, dated June 7, 2023 (ECF 171) ("Supp. Rodriguez Decl.") responding to Dr. Darrin Mangiacarne's declaration in opposition to plaintiffs' motion for a preliminary injunction.

2. In this declaration, I summarize data and literature regarding OUD and MOUD that have been published since my prior declarations.

The Opioid Crisis (Updated Data)

3. In my May 3, 2023 declaration, I provided statistics about the extent and severity of the opioid crisis in the United States. *See* Rodriguez Decl. ¶¶30-32. Data that have become available since then demonstrate that the opioid crisis has gotten worse.

4. Results from the 2022 National Survey on Drug Use and Health (NSDUH) published November 13, 2023, showed that about 6.1 million people in the United States who are

12 years old or older had an opioid use disorder (1). That is more than *double* the 2.7 million people who had an opioid use disorder in 2020. *See* Rodriguez Decl. ¶30. According to the Centers for Disease Control, 220 people died each day from opioid overdoses in 2021 (2), an increase from the 187 deaths per day in 2020 cited in my prior declaration. *See* Rodriguez Decl. ¶30. The number of people who died from an opioid overdose increased more than 15% from 2020 to 2021 – with heroin-involved death rates decreasing by nearly 32% and fentanyl-involved deaths increasing by over 22% in one year (2). Nearly 88% of opioid-related overdose deaths involve fentanyl (3). Given the increases in opioid use disorder and opioid deaths in the most recent years of available data, these numbers are likely higher now.

5. In Massachusetts, based on the data available as of October 19, 2023, there were 2,331 confirmed opioid-related overdose deaths in 2022 (4). That is an increase from the 2,281 confirmed opioid-related deaths in 2021 cited in my prior declaration. *See* Rodriguez Decl. ¶31. In 2022, there were 2,170 opioid-related overdose deaths where a toxicology screen was also available. Among these deaths, on average fentanyl was present in 93%, cocaine in 53%, benzodiazepines in 27%, alcohol in 28%, prescription opioids in 11%, heroin in 6%, xylazine in 5%, and amphetamines in 9% (4).

The Importance of Access to Medications for Opioid Use Disorder

6. In my May 3, 2023 declaration, I described treatment for opioid use disorder (OUD), including medication for opioid use disorder (MOUD), and I summarized the standard of care and literature demonstrating the efficacy of MOUD. Recent literature reinforces and strengthens the medical and academic consensus that access to all three forms of MOUD (buprenorphine, methadone, and naltrexone) is necessary to meet the standard of care for individuals with OUD and that "agonist" (buprenorphine and methadone) MOUD outperforms other forms of treatment in outcomes including overdose deaths. *See* Rodriguez Decl. ¶¶33-50.

7. For example, a retrospective cohort study in Connecticut published in January 2024 reviewed relative risk of death following exposure to MOUD compared to no treatment (5). This study found that exposure to buprenorphine or methadone treatment reduced the relative

risk of death by 34% and 38%, respectively; whereas for individuals who received non-medication treatments (including both short term (≤14 days) or long term (≥ 21 days) treatment) the relative risk of death was equal *or worse* to those who received *no treatment at all* (5). In other words, non-MOUD treatments provided no protection against overdose death. (Data on exposure to naltrexone was not available.) This finding suggests that non-MOUD treatment may actually be inferior in preventing overdose death to no treatment at all (5).

8. The results of the Connecticut study are consistent with other studies. For example, a study published in February of 2020 using data in a national database evaluated the effectiveness of MOUD (buprenorphine/methadone or naltrexone) compared to nonpharmacologic treatment such as no treatment, inpatient detoxification/residential services, intensive behavioral health, or nonintensive behavioral health (i.e. outpatient counseling) and found the following results (6):

a) Only individuals receiving MOUD treatment with buprenorphine or methadone were less likely to experience an overdose compared with those receiving no treatment: The study found that MOUD treatment with buprenorphine or methadone was associated with 76% reduction in overdose at 3 months and a 59% reduction at 12 months (6).

b) Buprenorphine and methadone were also protective in reducing serious opioid-related acute care use during a 3 month follow up period and at 12 months. MOUD treatment with buprenorphine or methadone was associated with a 32% relative rate of reduction at 3 months and 26% at 12 months compared with no treatment (6).

c) Inpatient detoxification or residential services treatment, intensive behavioral health, and naltrexone treatment were **not** significantly associated with overdose or serious opioid related acute care use at 3 or 12 months compared to no treatment – meaning those treatments provided **no** significant protection against overdose or serious opioid-related acute care use (6).

d) Compared to groups treated with buprenorphine or methadone, **all** other treatment groups (including treatment with naltrexone or intensive behavioral health services) were more likely to have a posttreatment admission to inpatient detoxification in the 3 month and 12 month follow up period (6).

e) Treatment retention matters: Individuals who received methadone or buprenorphine treatment for more than six months had lower overdose and serious acute care opioid-related use than those who received shorter treatment durations or no treatment at all (6).

9. Other studies published since my previous declarations reinforce the effectiveness and importance of buprenorphine and methadone MOUD. A study published in August of 2023 examined the differential impact of MOUD (naltrexone, buprenorphine, and methadone) on drug overdose-related hospitalization or emergency room visits in individuals with opioid use disorder (OUD) (7). This study found that only 10.38% of individuals with OUD received MOUD. Buprenorphine was associated with the lowest risk of drug overdose-related hospitalizations and emergency department visits compared to methadone and naltrexone (7). The low percentage of individuals with OUD receiving MOUD, which has been shown in other studies, highlights a need for access for all MOUD treatment options. The authors concluded: "Increasing the availability of MAT to patients with OUD is a key step toward preventing relapse and reducing overdose-related ER visits and hospitalizations." (7)

10. The importance of MOUD treatment and of continuation of treatment without interruption were also highlighted by a study published in May of 2023, which found that among individuals with OUD, the risk of overdose events during the 24 weeks after starting MOUD was highest in those who did not initiate medication treatment or who discontinued medication treatment (8). The length of the discontinuation of treatment did not have a significant effect, meaning that any interruption in treatment, even for a brief period, could increase the risk of overdose (8). This study also highlighted real-life experience with difficulties in extended-release naltrexone (XR-NTX) initiation: More than a quarter (27.9%) of individuals assigned to the

naltrexone treatment arm did not initiate the medication, compared to only 2.2% of those assigned to buprenorphine and 1.7% of those assigned to methadone who did not initiate those medications (8). The overdose rate in those who did not initiate naltrexone (XR-NTX) was more than two times higher than in those who were able to start the medication (8.9% versus 3.9%) (8). The study highlights that any practice that involves requiring individuals to be on only one form of MOUD, especially if it requires interruption in treatment and especially if the only form of MOUD permitted is naltrexone, can significantly expose that individual to an increase in overdose risk.

11. The importance of buprenorphine or methadone MOUD on readmissions and morbidity has also continued to be emphasized in medical literature. A study accepted for publishing in January of 2024 (available online prior to print) showed that receiving buprenorphine or methadone MOUD treatment during hospitalization and at discharge decreased odds of 30-day readmission by almost two thirds in individuals who inject drugs and present with injection drug use related infections (9).

12. Finally, a study available as of January 2024 reviewed the impact of MOUD on several treatment outcomes for individuals at OUD treatment facilities across the United States and found that over 18 months, compared to patient-reported estimates at baseline, MOUD treatment was associated with an increase in rates of abstinence, and decreases in rates of opioid-related overdose, emergency department visits, and arrests, again demonstrating the importance of access and treatment with MOUD (10). Notably, relatively few people in this study were receiving naltrexone, so most of the results are associated with buprenorphine or methadone treatment exposure (10).

13. In sum, the data continue to consistently demonstrate that expanded access to all FDA-approved forms of MOUD, and in particular access to buprenorphine and methadone, is critical to confronting the opioid crisis. *See* Rodriguez Decl. ¶¶104-107.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed this 30 day of January 2024, at Sunrise, Florida.

DocuSigned by:
F69A7214844E4EB...

Claudia P. Rodriguez, MD

References:

1. Substance Abuse and Mental Health Services Administration. (November 13, 2023). Results from the 2022 National Survey on Drug Use and Health: A companion infographic (SAMHSA Publication No. PEP23-07-01-007). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/data/report/2022-nsduh-infographic

2. Centers for Disease Control and Prevention (August 8, 2023). Understanding the Epidemic. Retrieved from: https://www.cdc.gov/opioids/basics/epidemic.html. January 21, 2024.

3. Centers for Disease Control and Prevention (August 22, 2023). Drug Overdose Deaths. Retrieved from: https://www.cdc.gov/drugoverdose/deaths/index.html. January 21, 2024.

4. Data Brief: Opioid-Related Overdose Deaths among Massachusetts Residents. Massachusetts Department of Mental Health (December 2023). Retrieved from: https://www.mass.gov/doc/opioid-related-overdose-deaths-among-ma-residents-december-2023/download. Accessed January 21, 2024.

5. Heimer R, Black AC, Lin H, Grau LE, Fiellin DA, Howell BA, Hawk K, D'Onofrio G, Becker WC. Receipt of opioid use disorder treatments prior to fatal overdoses and comparison to no treatment in Connecticut, 2016-17. Drug Alcohol Depend. 2024 Jan 1;254:111040. doi: 10.1016/j.drugalcdep.2023.111040. Epub 2023 Nov 28. PMID: 38043226.

6. Wakeman SE, Larochelle MR, Ameli O, et al. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. *JAMA Netw Open.* Feb 5, 2020;3(2):e1920622. doi:10.1001/jamanetworkopen.2019.20622

7. Bahrami K, Kuo YF, Digbeu B, Raji MA. Association of Medication-Assisted Therapy and Risk of Drug Overdose-Related Hospitalization or Emergency Room Visits in Patients With Opioid Use Disorder. Cureus. 2023 Aug 26;15(8):e44167. doi: 10.7759/cureus.44167. PMID: 37753052; PMCID: PMC10519365.

8. Brandt L, Hu MC, Liu Y, Castillo F, Odom GJ, Balise RR, Feaster DJ, Nunes EV, Luo SX. Risk of Experiencing an Overdose Event for Patients Undergoing Treatment With Medication for Opioid Use Disorder. Am J Psychiatry. 2023 May 1;180(5):386-394. doi: 10.1176/appi.ajp.20220312. Epub 2023 Mar 9. PMID: 36891640.

9. Robertson NM, Mangino AA, South AM, Fanucchi LC. Medications for opioid use disorder associated with reduced readmissions for patients with severe injection-related infections: A matched cohort study. J Subst Use Addict Treat. 2024 Jan 21:209298. doi: 10.1016/j.josat.2024.209298. Epub ahead of print. PMID: 38262559.

10. Dever JA, Hertz MF, Dunlap LJ, Richardson JS, Wolicki SB, Biggers BB, Edlund MJ, Bohm MK, Turcios D, Jiang X, Zhou H, Evans ME, Guy GP Jr. The Medications for Opioid Use Disorder Study: Methods and Initial Outcomes From an 18-Month Study of Patients in Treatment for Opioid Use Disorder. Public Health Rep. 2024 Jan 25:333549231222479. doi: 10.1177/00333549231222479. Epub ahead of print. PMID: 38268479.